RULE ANALYSIS

Introduction: **THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE**

Short Title: Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

Rule Number: §291.76

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

(1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, update references to DEA 222 form requirements to be consistent with federal regulations.

The Board reviewed and voted to propose the amendments during the February 2, 2021 meeting. The proposed amendments were published in the April 2, 2021, issue of the *Texas Register* at 46 TexReg 2159.

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

The Texas State Board of Pharmacy proposes amendments to §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments, if adopted, update references to DEA 222 form requirements to be consistent with federal regulations.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure consistency between Board rules and federal regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.

(4) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(5) Board--The Texas State Board of Pharmacy.

(6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug

immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

(vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the ASC;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection;

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC; and

(xiv) ensuring that a pharmacist visits the ASC at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license.

(K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(2) Environment.

(A) General requirements.

(i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs and controlled substances, and to security of records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules;

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ASC.

(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the ASC;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the ASC to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date;

(-d-) quantity of the drug, if quantity is greater than one; and

(-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for prepackaging the drug.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the prepacker;

(-j-) signature or electronic signature of the responsible pharmacist; and

(-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the prepackaged drug.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the practitioner's medication order.

(C) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

(i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy.

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity taken;

(V) time and date; and

(VI) signature or electronic signature of person making withdrawal.

(iv) The medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph.

(v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy;

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices; and

(iii) The pharmacist shall conduct an audit of the patient's medical record according to the schedule set out in the policy and procedures at a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable for removing drugs or devices in the absence of a pharmacist.

(A) Prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container.

(B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(C) A record shall be made at the time of withdrawal by the authorized person removing the drug or device; the record shall contain the following information:

(i) name of the drug, strength, and dosage form;

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal.

(D) A pharmacist shall verify the withdrawal according to the following schedule.

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(iii) The medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated medication supply systems;

(T) use of data processing systems; and

(U) drug regimen review.

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the ASC.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility, and necessary auxiliary labels) by the pharmacy provided, however, that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

(C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subparagraph, "readily retrievable" means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(D) Records, except when specifically required to be maintained in original or hard copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system provided:

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V, shall include the following information:

(i) patient's name;

(ii) practitioner's name who ordered the drug;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) signature or electronic signature of individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records.

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as an employee or consultant/full or part-time pharmacist of the ASC.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

(3) General requirements for records maintained in a data processing system.

(A) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure.

(C) A pharmacy that changes or discontinues use of a data processing system must:

(i) transfer the records to the new data processing system; or

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

(D) Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(F) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(G) An audit trail printout for each strength and dosage form of the drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

(B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(i) the actual date of distribution;

(ii) the name, strength, and quantity of controlled substances distributed;

(iii) the name, address, and DEA registration number of the distributing pharmacy; and

(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(D) **A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.** [~~If the distribution is for a Schedule II controlled substance, the following is applicable.~~

~~(i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.~~

~~(ii) The distributing pharmacy shall:~~

~~(I) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";~~

~~(II) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and~~

~~(III) forward Copy 2 of the DEA order form (DEA 222) to the divisional office of DEA.~~]

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used. Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

[~~(B) Copy 3 of DEA order forms (DEA 222), which have been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked records for that order;~~

~~(C) a copy of the power of attorney to sign DEA 222 order forms (if applicable);~~]

(B) [~~(D)~~] suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory;

(C) [~~(E)~~] supplier's credit memos for controlled substances and dangerous drugs;

(D) [~~(F)~~] a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a copy of the perpetual inventory on-site;

(E) [~~(G)~~] reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(F) [~~(H)~~] records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) [~~(I)~~] a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

(i) reports of theft or significant loss of controlled substances to DEA and the board;

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(ii) The pharmacy maintains a copy of the notification required in this subparagraph; and

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(C) Access to records. If the records are kept in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.